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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,415	11/21/2001	Anneli Attersand	10806-152	3650

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/990,415	ATTERSAND, ANNELI	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/07/02,3/5/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In the response to restriction requirement filed December 2, 2003, Applicant's election with traverse of Group I, claims 1, 4-7 and 9, drawn to a nucleic acid, a vector comprising the nucleic acid, a host cell comprising the vector, and a process of producing a polypeptide, and SEQ ID NO:1 is acknowledged. The traversal is on the ground(s) that claims 2 and 3 are drawn to a polypeptide encoded by a nucleic acid, and claim 8 is drawn to a method for identifying an agent capable of modulating a nucleic acid; the invention is related to the identification of a human gene family, where genes encode a group of polypeptides referred as "protein cluster I", which shows a high degree of conservation in two separate regions; and the search can be made without serious burden to include all the claims, and all nucleotide sequences (SEQ ID NOs:1, 3, 5 and 7). This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no search burden. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups and sequences would require search of classes and sequences unnecessary for the examination of the elected claims. For example, if SEQ ID NOs:3, 5 and 7 were included, it would require search of additional nucleotide sequences, and if claims 2 and 3 were included, it would require additional search of class 530, subclass 350. Therefore, coexamination of each of these inventions would require a serious additional burden of search. However, upon reconsideration, claims 2 and 3, and SEQ ID

NO:2, directed to a polypeptide encoded by the nucleotide, are included for examination, thus, claims 1-7 and 9, and SEQ ID NOs:1 and 2 are examined.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on

the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification cites a web address (at pages 8-13) in the form of a hyperkink and/or other forms of browser-executable code, which is impermissible and require deletion. Appropriate correction is required.

Claim Objections

3. Claims 1 and 3 are objected to because the claim contains recitation of non-elected nucleotide and amino acid sequences. Claim 3 is also objected to because the claim does not end with a period ".".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-7 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a polynucleotide comprising SEQ ID NO:1 or SEQ ID NO:1 related nucleotide (claim 1); a polypeptide encoded by the polynucleotide or a polypeptide comprising an amino acid sequence of SEQ ID NO:2 (claims 2, 3); a vector

comprising the polynucleotide (claims 4, 5); a host cell comprising the vector (claims 6 and 9); and a method of producing the polypeptide (claim 7). The polypeptide of SEQ ID NO:2 is referred as a member of the family of Protein Cluster I (Example 1), however, the function of the protein or the gene encoding the protein has not been identified. The specification indicates the alignment of the proteins in the Protein Cluster I showed a high degree of conservation in two separate regions indicating the presence of two novel domains (Table I, Example 2); the sequence search indicates SEQ ID NO:1 has 88% and 79% sequence identity, respectively, to two genes that encode a putative rat tricarboxylate carrier protein (page 11, paragraph 4, Example 2); and expression analysis of SEQ ID NO:1 indicates this nucleotide is mainly expressed in the nerve and digestion systems (page 12, Example 3). The prior art also indicates SEQ ID NO:1 has 70.6% homology to SEQ ID NO:1343, and SEQ ID NO:2 has 100% homology to SEQ ID NO:1344 (see attached sequence match; Leach et al., US 2002/0082206), where SEQ ID NO:1344 may be similar to a rat tricarboxylate carrier fragment (column 22); and SEQ ID NO:1 has 76.6% homology to SEQ ID NO:1016 (see attached sequence match; Tang et al., U. S. Patent 6,569,622), where SEQ ID NO:1016 encodes a protein having 99% similarity to a rat tricarboxylate carrier (columns 175-176). However, the specification does not identify the protein of SEQ ID NO:2 as a tricarboxylate carrier or as a member of any known protein family, nor demonstrates the activity or function of the protein or nucleotide encoding the protein. Although the specification identifies the tissues having the expression of SEQ ID NO:1, e.g., the tissues of nervous and digestive systems (Example 3), and indicates the invention is to identify genes involved in metabolic disorders (page 3, first paragraph), the direct correlation between the metabolic disorder

and the protein is not demonstrated. For these reasons, the instant invention does not possess a specific or a well-established utility, although there is a general utility that is applicable to the broad class of proteins. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, production of antibodies to identify other related proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 and 9 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(e) as anticipated by Tang *et al.* (U. S. Patent 6,569,662, filed July19, 2000).

Tang *et al.* teach an isolated polynucleotide of SEQ ID NO:1016 (1729 nucleotides; columns 175-176) contains a nucleotide sequence (nucleotides 247-1029) encoding SEQ ID NO:2 (see attached sequence match), and the polynucleotide also includes a nucleotide that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 (column 3, lines 4-15; claim 1 (b)); an isolated polypeptide that is encoded by the nucleotide that hybridizes under stringent hybridization conditions to the complement of SEQ ID NO:1016 (column 3, lines 24-32; claim 2); an expression vector containing the nucleotide and a host cell transformed with the expression vector (column 2, lines 47-60; claims 4-6 and 9); and a method of producing a polypeptide by culturing a host cell comprising the vector under conditions to produce the polypeptide (column 3, lines 51-58; claim 7).

7. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(e) as anticipated by Leach *et al.* (US 2002/0082206, priority date May 30, 2000).

Leach *et al.* teach an isolated polynucleotide of SEQ ID NO:1343 (1375 nucleotides; paragraph [0005]) and an isolated polypeptide SEQ ID NO:1344 (266 amino

acid) encoded by the nucleic acid sequence (paragraph [0009]), where SEQ ID NO:1344 has 100% sequence identity to SEQ ID NO:2 (see attached sequence match; column 3, lines 24-32; claims 2 and 3), and it would be expected that the polynucleotide of SEQ ID NO:1343 comprises a nucleotide capable of hybridizing under stringent hybridization conditions to the complement of the polypeptide coding region of SEQ ID NO:1 because both SEQ ID NO:1 and SEQ ID NO:1343 encodes a polypeptide having SEQ ID NO:2 (claim 1 (b)); an expression vector containing the nucleotide and a host cell transformed with the expression vector (paragraphs [0006] and [0007]; claims 4-6 and 9); and a method of producing a polypeptide by culturing a host cell comprising the vector under conditions to produce the polypeptide (paragraph [00012]; claim 7).

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
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TECHNOLOGY CENTER 1600

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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February 5, 2004